

Listing of the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

- 1-21. (Canceled)
22. (Previously amended) A method of producing a dry powder formulation for inhalation, said formulation having a fine particle fraction (FPF) with reduced sensitivity to penetrating moisture, and comprising a pharmaceutically inactive carrier comprising particles of noninhalable size and a pharmaceutically active component comprising at least one finely-divided pharmaceutically active compound comprising particles of inhalable size; said method comprising: mixing together (i) said pharmaceutically inactive carrier; (ii) said pharmaceutically active component; and (iii) pulverulent magnesium stearate, which is present in an amount effective to provide the FPF with reduced sensitivity to penetrating moisture and to stabilize the dry powder formulation.
23. (Previously presented) The method of claim 22, comprising mixing by tumble blending.
24. (Previously presented) The method of claim 22, comprising first mixing the carrier with the magnesium stearate and then admixing the pharmaceutically active component therewith.
25. (Previously presented) The method of claim 22, comprising first mixing the carrier with the pharmaceutically active component and then admixing the magnesium stearate therewith.
26. (Previously presented) The method of claim 22, wherein the pharmaceutically active compound is a hygroscopic compound capable of absorbing at least 0.5% by weight of its own weight of absorptively bound water when stored in air having a relative humidity of 50%.
27. (Previously presented) The method of claim 22, wherein the pharmaceutically active compound is a hydrophilic compound having a wetting angle of less than 90°.
28. (Previously presented) The method of claim 22, wherein the pharmaceutically active compound is a hydrophilic compound having a wetting angle of less than 70°.

29. (Previously presented) The method of claim 22, wherein the pharmaceutically active compound is formoterol or a pharmaceutically acceptable salt thereof.
30. (Previously presented) The method of claim 22, wherein the pharmaceutically active compound is selected from the group consisting of formoterol fumarate, formoterol tartrate, ipratropium bromide and tiotropium bromide.
31. (Previously presented) The method of claim 22, wherein the pharmaceutically active component further comprises a second pharmaceutically active compound having particles of inhalable size.
32. (Currently amended) The method of claim 31, wherein the pharmaceutically active component comprises ~~is selected from the group consisting of~~
 - a) a compound selected from the group consisting of formoterol fumarate, formoterol tartrate, levalbuterol sulfate and salmeterol xinafoate, and
 - b) a corticosteroid.
33. (Previously presented) The method of claim 22, wherein the pharmaceutically active compound has a mean particle size of 1 to 10 μm .
34. (Previously presented) The method of claim 22, wherein the pharmaceutically active compound has a mean particle size of 1 to 6 μm .
35. (Previously presented) The method of claim 22, wherein the magnesium stearate is present in an amount of 0.1 to 2% by weight, based on the total weight of the formulation.
36. (Previously presented) The method of claim 22, wherein the magnesium stearate is present in an amount of 0.25 to 1% by weight, based on the total weight of the formulation.
37. (Previously presented) The method of claim 22, wherein the magnesium stearate is present in an amount of 0.4 to 0.8% by weight, based on the total weight of the formulation.
38. (Previously presented) The method of claim 22, wherein the carrier is selected from the group consisting of monosaccharides, disaccharides, sugar alcohols, polylactic acid and cyclodextrin.

39. (Previously presented) The method of claim 22, wherein the carrier is selected from the group consisting of glucose, lactose monohydrate and trehalose.

40. (Previously presented) The method of claim 22, wherein the carrier particles have a mass mean aerodynamic diameter of 10 to 500 μm .

41. (Previously presented) The method of claim 22, wherein the carrier particles have a mass mean aerodynamic diameter of 50 to 200 μm .

42. (Previously presented) The method of claim 22, further comprising admixing particles of micronized lactose monohydrate wherein at least 50% of the particles thereof have a maximum particle size of 10 μm , with said carrier, said pharmaceutically active component and said magnesium stearate.

43. (Currently amended) A method of stabilizing ~~against penetrating moisture~~ a fine particle fraction (FPF) of a dry powder formulation for inhalation, said formulation comprising a pharmaceutically inactive carrier and a finely-divided pharmaceutically active compound; said method comprising: mixing said carrier having particles of noninhalable particle size, said pharmaceutically active compound having particles of inhalable particle size and pulverulent magnesium stearate, which is present in an amount effective to stabilize the FPF of the formulation against penetrating moisture.

44. (Currently amended) A dry powder inhaler ~~having reduced moisture sensitivity~~, comprising

- a) a powder reservoir containing a dry powder formulation having reduced moisture sensitivity comprising:
 - i) a pharmaceutically inactive carrier having particles of noninhalable particle size,
 - ii) a pharmaceutically active component comprising at least one finely divided pharmaceutically active compound having particles of inhalable particle size, and
 - iii) magnesium stearate; and

- b) means for delivering metered doses of the pharmaceutically active compound for inhalation.
45. (Previously presented) The dry powder inhaler of claim 44, wherein the pharmaceutically active compound is a hygroscopic compound capable of absorbing at least 0.5% by weight of its own weight of absorptively bound water when stored in air having a relative humidity of 50%.
46. (Previously presented) The dry powder inhaler of claim 44, wherein the pharmaceutically active compound is a hydrophilic compound having a wetting angle of less than 90°.
47. (Previously presented) The dry powder inhaler of claim 44, wherein the pharmaceutically active compound is a hydrophilic compound having a wetting angle of less than 70°.
48. (Previously presented) The dry powder inhaler of claim 44, wherein the magnesium stearate is present in an amount of 0.1 to 2% by weight, based on the total weight of the formulation.
49. (Previously presented) The dry powder inhaler of claim 44, wherein the magnesium stearate is present in an amount of 0.25 to 1% by weight, based on the total weight of the formulation.
50. (Previously presented) The dry powder inhaler of claim 44, wherein the magnesium stearate is present in an amount of 0.4 to 0.8% by weight, based on the total weight of the formulation.
51. (Previously presented) The dry powder inhaler of claim 44, wherein the carrier is selected from the group consisting of monosaccharides, disaccharides, sugar alcohols, polylactic acid and cyclodextrin.
52. (Previously presented) The dry powder inhaler of claim 44, wherein the carrier is selected from the group consisting of glucose, lactose monohydrate and trehalose.

53. (Previously presented) The dry powder inhaler of claim 44, wherein the formulation further comprises particles of micronized lactose monohydrate wherein at least 50% of the particles thereof have a maximum particle size of 10 μm .

54. (Previously presented) The dry powder inhaler of claim 44, wherein the pharmaceutically active compound is formoterol or a pharmaceutically acceptable salt thereof.

55. (Previously presented) The dry powder inhaler of claim 44, wherein the pharmaceutically active compound is selected from the group consisting of formoterol fumarate, formoterol tartrate, ipratropium bromide and tiotropium bromide.

56. (Previously presented) The dry powder inhaler of claim 44, wherein the formulation further comprises a second pharmaceutically active compound having particles of inhalable size.

57. (Previously presented) The dry powder inhaler of claim 44, wherein the pharmaceutically active component comprises

- a) a member selected from the group consisting of formoterol fumarate, formoterol tartrate, levalbuterol sulfate and salmeterol xinafoate, and
- b) a corticosteroid.

58. (Previously presented) A dry powder formulation for inhalation, comprising:

- a) a pharmaceutically inactive carrier having particles of noninhalable particle size,
- b) at least two finely divided pharmaceutically active compounds having particles of inhalable particle size, and
- c) magnesium stearate adhering to said particles of said pharmaceutically inactive carrier, the magnesium stearate being in an amount of 0.1 to 2% by weight, based on the total weight of the formulation, said amount being sufficient to provide the formulation with an improved resistance to moisture.

59. (Previously presented) The formulation of claim 58, wherein one pharmaceutically active compound is selected from the group consisting of formoterol fumarate, formoterol tartrate, levalbuterol sulfate and salmeterol xinafoate, and a second pharmaceutically active compound is a corticosteroid.

60. (Previously presented) The formulation of claim 58, wherein the magnesium stearate is present in an amount of 0.25 to 1% by weight, based on the total weight of the formulation.

61. (Previously presented) The formulation of claim 58, further comprising particles of micronized lactose monohydrate wherein at least 50% of the particles thereof have a maximum particle size of 10 μm .

62. (Previously presented) The dry powder inhaler of claim 44, said inhaler comprising a multidose reservoir.

63. (Previously presented) The dry powder inhaler of claim 44, said inhaler comprising a dry powder predosed unit.

64. (Previously presented) The dry powder inhaler of claim 63, wherein said predosed unit is in the form of a capsule.

65. (Previously presented) The method of claim 22, wherein said formulation exhibits a reduction in FPF by at least 50% within 10 days of storage at 40°C and 75% relative atmospheric humidity.

66. (Previously presented) The method of claim 43, wherein said formulation exhibits a reduction in FPF by at least 50% within 10 days of storage at 40°C and 75% relative atmospheric humidity.

67. (Previously presented) The inhaler of claim 44, wherein said dry powder formulation of a) comprises a fine particle fraction (FPF), said formulation exhibiting a reduction in said FPF by at least 50% within 10 days of storage at 40°C and 75% relative atmospheric humidity.

68. (Previously presented) The formulation of claim 58, said formulation comprising a fine particle fraction (FPF) and exhibiting a reduction in said FPF by at least 50% within 10 days of storage at 40°C and 75% relative atmospheric humidity.